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Patent and Trademark Office**

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OCT - 6 1994

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Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fisher's Lane, Room 11-44  
Rockville, MD 20857

Re: Zerit

FDA Docket No. 94E-0332

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,978,655 issued December 18, 1990. The application was filed on August 19, 1994, under Title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office on the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 USC § 156(d)(2)(A).

*C. E. Van Horn*

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Charles E. Van Horn  
Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Dominic M. Mezzapelle  
Associate General Counsel-Patents  
Bristol-Myers Squibb Company  
345 Park Avenue  
New York, NY 10154